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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,247	11/25/2003	David Bar-Or	4172-82	3907

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EXAMINER	
LIU, SAMUEL W	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,247	BAR-OR, DAVID	
	Examiner	Art Unit	
	Samuel W. Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-75 and 78-185* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-75 and 78-185* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-75 and 78-185 are pending

Applicants' preliminary amendment filed 6/28/04, which cancels claims 76-77, amends claims 22-23, 33-35, 45, 78, 97, 101, 111, 113, 124, 135, 137, 160, 162, 178 and 180, and adds claims 183-184, has been entered.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121 :

1. Claims 1-35, 82-97, 101-105 and 140-141, drawn to a method of treating a disease mediated by increased phosphorylation comprising administering to a subject an extracellualr phosphate-acceptor compound (EPAC), are classified in class 514, subclass, 2.

2. Claims 36-45, drawn to a method of treating cancer comprising administering to a subject a phosphate acceptor compound (PAC), are classified in class 514, subclass 2.

3. Claims 46-75, 79 and 80-81, drawn to (i) a pharmaceutical composition comprising PAC, (ii) a solution for contacting a tissue or organ that has been removed from an animal comprising EPAC, and (iii) a kit for contacting a tissue or organ that has been removed from an ammonal comprising combination of EPAC molecules wherein the plurality of said EPAC molecules differ from one other, and a container for EPAC molecules, are classified in class 514, subclass 2, and class 530, subclass 340.

4. Claims 183-185 and 78, drawn to a method of inhibiting increased phosphorylation in a cell, a tissue or organ that has been removed from an animal comprising contacting the cell, a tissue or organ with a solution containing EPAC molecule, are classified in class 514, subclass 2.

5. Claims 98-100, drawn to a method of whitening teeth of an animal comprising contacting the mouth tissue of said animal with the EPAC molecule, are classified in class 514, subclass 2.

6. Claims 106-115, 127-131 and 135-139, drawn to an oral care product which is an oral care device or suture or strip, comprising the EPTA molecule, and a kit comprising said oral product, are classified in class 514, subclass 2, class 424, subclass 278.1, and class 530, subclass 340.

7. Claims 116-126 and 132-134, drawn to an oral care composition comprising EPAC molecule and the tooth whitening composition, and a kit comprising said oral product, are classified in class 514, subclass 2, class 424, subclass 278.1, and class 530, subclass 340.

8. Claims 142-151 and 165-169, drawn to a personal care product which is personal care device, product comprising the EPAC molecule, and a kit comprising said oral product, are classified in class 514, subclass 2, class 424, subclass 278.1, and class 530, subclass 340.

9. Claims 152-164 and 170-182, drawn to a personal care composition comprising the EPAC molecule and suntan cream, and a kit comprising said oral product, are classified in class 514, subclass 2, class 424, subclass 278.1, and class 530, subclass 340.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-2, 4 and 5 are directed to different and/or distinct methods. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of Inventions I and II since they constitute patentably distinct inventions comprising methodologies, starting material, objectives, technical considerations, ingredients, endpoint or/and treatment outcome. Therefore, each method is patentably distinct.

Inventions 3 6, 7, 8 and 9 are patentably distinct from one another because of the materially different structures of the compounds claimed. The Group 3 composition comprising the PAC or EPAC molecule which differs from the products/composition of Groups 6-9 in that the Group 3 composition is neither an oral care composition (Group 7), an oral care product (Group 6), a personal care composition (Group 9), nor a personal care product (Group 8).

The product/composition of Groups 6-7 differ from those of Groups 8-9 in that the formers refer to the oral care product/composition while the later to the personal care

product/composition. The product of Group 6 differs from the composition of Group 7 in that the former is a device while the latter is not. Similarly, the Group 8 product is a personal care device whereas the Group 9 composition does not comprise said device.

Thus, the products/compositions that are the subject of each group are independent and/or patentable distinct from each other because each product/composition is structurally distinct. They would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Invention 3 is related to Invention 1, 2, 4 or 5 as product and processes of use (note that, in Group II, the method of step comprises use of the test compound which is the modulator compound upon the deification/characterization). The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the Group 3 PAC or EPAC molecule can be used to raising an antibody which specifically bind the molecule thereof, for example.

Invention 6 is unrelated to Inventions 1, 2, 4 or 5. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the oral care device of group 6 is not required for the processes of Groups 1-2 and 4-5.

Invention 7 is unrelated to Inventions 1, 2, 4 or 5. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the oral care composition of group 7 is not required for or used in the processes of Groups 1-2 and 4-5.

Invention 8 is unrelated to Inventions 1, 2, 4 or 5. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the personal care product of group 8 is not required for or used in the processes of Groups 1-2 and 4-5.

Invention 9 is unrelated to Inventions 1, 2, 4 or 5. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the personal care composition of group 9 is not required for or used in the processes of Groups 1-2 and 4-5.

Additional Election

Applicant is required under 35 US 121 (1) to elect a molecule or a disease state to which claims are restricted; and (2) to list all claims readable thereon including those subsequently added.

- If Group 1 is elected, applicant is required to elect (i) one disease state from claims 22-35, 91-93 and 95-96, because the diseases/conditions set forth in these claims are pathologically distinct/different, and treatment and outcome thereof differ from one other; e.g., autoimmune disease is distinct from inflammatory disease or from skin burn condition; and (ii) one particular EPAC molecule from claims 8-17 and 101-105,because structure and function of casein (claims 8-10) is distinct from those of albumin (claims 11-12), for example, wherein both casein and albumin are considered to be the EPAC molecules of this application. If casein is elected, applicant is further required to elect one subtype casein molecule with sequence identifier from claims 8-10 and 17 because members of casein family which encompasses α-, β-, γ-, and κ-casein are highly diverse in structure (see page 3896 of Stewart et al. (1984) *Nucleic Acid Res.* 12, 3895-3907).

- If Group 3 is elected, applicant is required to elect one particular EPAC molecule from claims 54-64 because structure and function of casein is distinct from those of albumin, for example, wherein both casein and albumin are considered to be the EPAC molecules of this application.

- If Group 6 is elected, applicant is required to elect (i) one kind of product from claims 107-110 because the oral care device and dental floss are materially distinct from each other; and (ii) one particular EPAC molecule from claims 112-115 and 135-139 because structure and function of casein is distinct from those of albumin, for example, wherein both casein and albumin are considered to be the EPAC molecules of this application. If casein is elected, applicant is further required to elect one subtype casein molecule with sequence identifier from claims 113-115 and 137-139 because members of casein family which encompasses α-, β-, γ-, and κ-casein are highly diverse in structure (see page 3896 of Stewart et al. (1984) *Nucleic Acid Res.* 12, 3895-3907).

• If Group 7 is elected, applicant is required to elect one particular EPAC molecule from claims 122-126 because structure and function of casein is distinct from those of phosvitin (a egg-yolk storage protein), for example, wherein both casein and phosvitin are considered to be the EPAC molecules of this application. If casein is elected, applicant is further required to elect one subtype casein molecule with sequence identifier from claims 124-126 because members of casein family which encompasses α-, β-, γ-, and κ-casein are highly diverse in structure (see page 3896 of Stewart et al. (1984) *Nucleic Acid Res.* 12, 3895-3907).

• If Group 8 is elected, applicant is required to elect one particular EPAC molecule from claims 147-151 and 160-164 because structure and function of casein is distinct from those of phosvitin (a egg-yolk storage protein), for example, wherein both casein and phosvitin are considered to be the EPAC molecules of this application. If casein is elected, applicant is further required to elect one subtype casein molecule with sequence identifier from claims 149-151 and 162-164 because members of casein family which encompasses α-, β-, γ-, and κ-casein are highly diverse in structure (see page 3896 of Stewart et al. (1984) *Nucleic Acid Res.* 12, 3895-3907).

• If Group 9 is elected, applicant is required to elect one particular EPAC molecule from claims 160-164 and 178-182, because structure and function of casein is distinct from those of phosvitin (a egg-yolk storage protein), for example, wherein both casein and phosvitin, are considered to be the EPAC molecules of this application. If casein is elected, applicant is further required to elect one subtype casein molecule with sequence identifier from claims 162-164 and 180-182 because members of casein family which encompasses α-, β-, γ-, and κ-casein are highly diverse in structure (see page 3896 of Stewart et al. (1984) *Nucleic Acid Res.* 12, 3895-3907).

It should be noted that this additional election of the restriction requirement is not species election but rather the additional election under 35 US 121 because of the reasons set forth above and because the above-mentioned disease states or conditions are distinct/different (e.g., inflammatory disease and skin burn condition in the additional election requirement for Group 1), and the EPAC molecules are structurally and/or functionally distinct/different (e.g., alpha casein protein is distinct from egg-yolk storage protein, phosvitin for Groups 11-13).

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The examiner can normally be reached Monday-Friday 9:00 -5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber, can be reached on (571) 272-0925. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Samuel Wei Liu, Ph.D.
March 7, 2006

JON WEBER
SUPERVISORY PATENT EXAMINER